UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,879	01/31/2002	Mark Ian Cockett	AHP 98089 D1	4886

25291 7590 06/04/2004

WYETH
PATENT LAW GROUP
FIVE GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/062,879	COCKETT ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/31/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment and election without traverse of Group II invention, claims 8-10 filed on 08 March 2004 is acknowledged. Following the amendment, claims 8-10 are amended, and the new claims 17-21 are added.

Currently, claims 1-21 are pending, and claims 8-10 and 17-21 are under consideration. Claims 1-7 and 11-16, as non-elected inventions, are withdrawn from consideration.

Formal Matters:

This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a Division of Application No. 09/178,109, filed on 23 October 1998." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9, 10, 18 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 9, 10, 18 and 19, as written, do not sufficiently distinguish over polypeptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified". See MPEP 2105.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 and 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "*the* Kv4.3 polypeptide" in line 4. There is insufficient antecedent basis for this limitation in the claim. Claim 17 is similarly indefinite.

Claim 9 is indefinite for the recitation of "comprising an amino acid sequence comprising the amino acid sequence of" in lines 1-2. The language "comprising the amino acid sequence of" is suggested. Claim 18 is similarly indefinite.

Claim 10 is indefinite for the recitation of "comprising *an* amino acid of SEQ ID NO:2", which indicates more than one SEQ ID NO:2. "Comprising *the* amino acid of SEQ ID NO:2" is suggested. Claim 19 is similarly indefinite.

Claim 20 is indefinite for the recitation of "an isolated amino acid *sequence*". "An isolated polypeptide whose amino acid sequence comprises ..." is suggested. Claim 21 is similarly indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 18, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a polypeptide of SEQ ID NO:2 or 4, does not reasonably provide enablement for claims to an allelic variant (claims 9 and 18), or % variant thereof (claims 20 and 21). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of

direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 9, 18, 20 and 21 encompass allelic or % variants of SEQ ID NO:2 or 4. The specification discloses merely *two* isoforms of human Kv4.3 polypeptides, which are primarily expressed in human heart (Example 3), and function as a potassium channel. No other variants of SEQ ID NO:2 or 4 meeting the limitations of these claims were ever identified or particularly described. The claims are broad because they do not require the claimed polypeptide to be identical to the disclosed sequence and because the claims have no functional limitation. Further, the specification does not teach the structural and functional relationship of the polypeptides, and provides no guidance or working examples as to how the skilled artisan could make an allelic variant, or a % variant with the functional property of Kv4.3, thus, it is not predictable that a randomly made variant would possess the desired functional activity. Furthermore, the specification does not teach one skilled in the art how to use an inactive polypeptide variant of SEQ ID NO:2 or 4, as no functional limitation associated with the variants in the claims. Therefore, it would require undue experimentation in order to make and use the claimed invention in its full scope.

Due to the large quantity of experimentation necessary to determine how to make a functional % or allelic variant, and how to use a % or allelic variant without said functional activity, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the lack of predictability of a functional variant, and the breadth of the claims which embrace inactive variant of SEQ ID NO:2 or 4, undue experimentation would be required of the skilled artisan to make and use the invention commensurate in scope with the claims

Claim 9, 18, 20 and 21 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to % and allelic variants of SEQ ID NO:2 or 4. The specification merely discloses *two* isoforms of human Kv4.3 polypeptides. No other variants of SEQ ID NO:2 or 4 meeting the limitations of these claims were ever identified or particularly described.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of SEQ ID NO:2 and 4, a skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides of SEQ ID NO:2 and 4, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 9, 18, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Dixon et al. (Circ Res. 1996, 79(4):659-68, provided by applicants).

Dixon discloses two rat Kv4.3 potassium channel polypeptides, locus KCD3_RAT, and locus P70622 (also see Figure 1). Dixon's locus KCD3_RAT is 99.7% identical to the present SEQ ID NO:2, and locus P70622 is 99.5% identical to the present SEQ ID NO:4 (see computer printout of the search results). As such, the cited sequences anticipate claims 20 and 21. Further, Dixon's polypeptides meet the limitation in claims 9 and 18 as being "an allelic variant" of SEQ ID NO:2 or 4, and therefore, also anticipate claims 9 and 18.

Claims 9, 18, 20 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bril et al., US6,368,823.

Bril discloses two human Kv4.3 potassium channel polypeptides, SEQ ID NO:2 and 4. Bril's SEQ ID NO:4 is 99.7% identical to the present SEQ ID NO:2, and SEQ ID NO:2 is 99.7% identical to the present SEQ ID NO:4 (see computer printout of the search results). As such, the cited sequences anticipate claims 20 and 21. Further, Dixon's polypeptides also anticipate claims 9 and 18 for the same reasons above.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Dong Jiang, Ph.D.
Patent Examiner
AU1646
5/27/04